REMARKS

35 U.S.C. § 112, First Paragraph Rejection

The Office Action rejected claims 1-24 under 35 U.S.C. § 112, first paragraph, stating that "there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented". The Applicant respectfully disagrees.

First, reference is made to M.P.E.P. § 2164.03 which states:

> The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification.

From this excerpt, it is noted that "the more predictable the art is, the less information needs to be explicitly stated in the specification".

Turning to the present specification, paragraphs [0025]-[0026] describe how to make a wound dressing as recited in claim 1. Paragraph [0023] describes how to use the wound dressing in accordance with the steps of claim 1. Regarding the language of the preamble of claim 1 reciting the prevention of alveolar osteitis and pain, a Declaration of the Inventor is attached. In Item 3 of the Inventor's Declaration, the inventor explains the predictability of the prevention of alveolar osteitis and pain in this art. Thus, it is submitted that specific examples regarding the prevention of alveolar osteitis and pain are not required in the specification to meet the enablement requirement. In particular, the prevention of alveolar osteitis and pain is predictable in this art and therefore "less information needs to be explicitly stated in the specification" as stated at M.P.E.P. § 2164.03.

It is respectfully requested that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

35 U.S.C. § 112, Second Paragraph Rejections

Claims 1 has been amended to state that alveolar osteitis and pain following tooth extraction or jaw cyst removal are prevented by the recited method steps.

Claims 6, 7, 9 and 10 have been amended to remove the indefiniteness regarding "mixtures thereof". Claims 16, 17, 19 and 20 have also been amended to remove this rejection.

Claim 12 has been amended to make it clear that the dressing is used in an oral cavity.

Claims 22-24 have been amended to delete the "for use" language as suggested in the Office Action.

Regarding the term "collagen derivative", it is defined at paragraph [0018] of the specification.

With respect to the term "crosslinking agent", it is a term known in the art. For example, a search for the term "crosslinking agent" in the USPTO "1976 to present" Patent Database turned up 23450 patents.

It is submitted that all of the rejections under 35 U.S.C. § 112, second paragraph, have been overcome.

35 U.S.C. § 103(a) Rejection

Claims 1-24 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,972,366 to Haynes *et al.* ("Haynes ") in view of U.S. Patent No. 6,063,061 to Wallace *et al.* ("Wallace ").

First, looking at Haynes, this patent describes a fibrous carrier matrix with a pharmaceutical composition. At column 2, lines 58-61, the matrix is described as follows:

"preferably the carrier is fibrous, such as a fabric dressing and suture or a cross-linked solid foam adsorbable implant". At column 4, lines 49-51 of Haynes, it is stated that "an example of a surgically implantable material which may be employed is the Gelfoam® brand absorbable gelatin sterile sponge". At column 4, line 66 to column 5, line 2 of Haynes, it is stated that "another example of a surgically implantable material which may be employed is the Surgicel® Absorbable Hemostat (Johnson & Johnson Medical, Inc., Arlington Tex.). This product comprises knitted fabric strips of oxidized regenerated cellulose".

It can be seen that throughout the patent, Haynes is describing a sponge material. In this regard, reference is also made to Item 4 of the attached Inventor's Declaration where the Inventor explains that collagen sponges are not flowable, lack any chemical or mechanical adhesive ability, and have only a 12 to 36 hour residence time in the oral cavity. As a result, collagen sponges are unable to achieve the intimate flow into bone interstices to provide a resilient, long lasting barrier to the oral environment.

In contrast, independent claims 1 and 12 of the present application require a "flowable" dressing which can provide the advantage of intimate flow into bone interstices to provide a resilient, long lasting barrier as stated in Item 4 of the attached Inventor's Declaration. Thus, all of the limitations of independent claims 1 and 12 (and the remaining claims that depend thereon) are not shown or suggested in Haynes.

Wallace was cited in the Office Action as teaching a method for liquefying the gelatin and the gel particles for loading into syringes. It is respectfully submitted that a *prima facie* case of obvious cannot be established using the Wallace patent.

At M.P.E.P. § 2143.01 VI., it is stated that

> "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references

are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)"

In Haynes, the described device is a sponge that may be "cut and worked" (see column 8, line 26 of Haynes). The Office Action contends that Wallace suggests liquefying the Haynes device. It is submitted that this modification would "would change the principle of operation" of the Haynes device. In other words, by liquefying the Haynes device, it could not be cut and worked as described in the Haynes patent. Accordingly, it is believed that Haynes and Wallace are "not sufficient to render the claims *prima facie* obvious" under the *In re Ratti test* cited above.

Accordingly, it is respectfully submitted that independent claim 1 (and claims 2-11 that depend thereon) and independent claim 12 (and claims 13-24 that depend thereon) are patentable over Haynes and Wallace.

Conclusion

It is believed that the entire application has been placed in condition for allowance.

No fees are believed to be due. However, if any fees are needed, please charge them to Deposit Account 17-0055.

Respectfully submitted,

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